

**REMARKS**

The Final Office Action mailed July 27, 2004, has been received and reviewed. Claims 1, 3, 10-20, 22, 28-61, and 64 are currently pending in the application. Claims 14, 17 through 20, 22, 28-33, 40, 42 through 46, 48-52, 54, 55, 57, 58, 60, and 61 have been withdrawn from consideration as being drawn to non-elected invention(s). Claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56, 59, and 64 stand rejected. The Office Action also indicates that claims 62 and 63 are "rejected," but both claims were canceled by previous amendment. Reconsideration is requested.

**35 U.S.C. § 103(a) Obviousness Rejections**

**Obviousness Rejection Based on U.S. Patent No. 5,728,396 to Peery et al. in View of U.S. Patent No. 5,446,108 to Jiang**

Claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56, 59, 62, and 63 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Peery et al. (U.S. Patent No. 5,728,396) in view of Jiang (U.S. Patent No. 5,446,108). Claims 62 and 63 were canceled by previous amendment and, thus, should not be included in the instant rejection. Applicants respectfully traverse the rejections as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The 35 U.S.C. § 103(a) obviousness rejections of each of claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56 and 59 is improper because a *prima facie* case of obviousness has not been established for any of the pending claims. The cited references do not alone, or in combination, teach or suggest each and every element of any of claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53,

56 and 59. Additionally, hindsight reconstruction has been used to argue obviousness and there is no suggestions to combine the references.

Independent claim 1 is directed to, *inter alia*, a **rate controlling membrane for an implantable drug delivery device** characterized by being subjected to an **elevated temperature** of about 30° C to about 5° C below the melting temperature of the **membrane**. Independent claim 41 is directed to, *inter alia*, a **rate controlling membrane for an implantable drug delivery device** characterized by being subjected to an **elevated temperature** of about 52° C to about 72° C, wherein the rate controlling membrane is subsequently incorporated into the drug delivery device. Independent claim 53 is directed to, *inter alia*, a **rate controlling membrane for an implantable drug delivery device** characterized by being subjected to an **elevated temperature** of about 45° C to about 80° C, wherein the rate controlling membrane is subsequently incorporated into the drug delivery device. Independent claim 56 is directed to a **rate controlling membrane for an implantable drug delivery device** characterized by being subjected to an **elevated temperature** of about 55° C- 75° C, wherein the membrane comprises a material selected from the group consisting of a polyurethane and polyether blocked amide group copolymer.

Thus, each of independent claims 1, 41, 53 and 56 is directed, *inter alia*, to a rate controlling membrane for an implantable drug delivery device, wherein the rate controlling membrane is characterized by being subjected to an elevated temperature. Peery et al. does not alone or in combination with Jiang teach or suggest and every element of any of independent claims 1, 41, 53 or 56, as required for obviousness. As expressly stated in the Final Office Action of July 27, 2004, "Peery et al. does not disclose that the rate controlling membrane is subjected to an elevated temperature below the melting temperature for a predetermined time and annealed." (Final Office Action, page 3). Regarding Jiang, the Final Office Action asserted

Jiang discloses polyamide polymers similar to those taught by Peery used in the making of surgical devices such as **drug delivery devices** that are **subjected to an elevated temperature** below the melting temperature for a predetermined time which is annealing, and subsequently incorporated into a delivery device (see, col. 3, line 31 to col.4, line 7 and col. 5, lines 14-50).

(*Id.*) (emphasis added).

However, Jiang does not disclose any structure for an implantable drug delivery device that is subjected to an elevated temperature as asserted in the Final Office Action. Rather, Jiang states “a suitable process for the manufacture of a **monofilament suture** comprises the operations of melt extruding the polymer herein to provide a **monofilament** and stretching the solidified **monofilament at an elevated temperature** in water ... Optionally, the **monofilament** can be **annealed** to provide a finished **suture**.” (Jiang, Col. 3, line 67 through Col. 4, line 3, and Col. 4, lines 5-7) (emphasis added). Thus, Jiang only discloses heating the **polymer** to form a **monofilament** or **suture** and does not teach or suggest a rate controlling membrane for an implantable drug delivery device, wherein the rate controlling membrane is characterized by being subjected to an elevated temperature as recited in each of independent claims 1, 41, 53 and 56. Further, Peery et al. and Jiang do not, alone or in combination, teach or suggest the particular temperatures or periods of time recited in any of independent claims 1, 41, 53 and 56. Since Peery et al. does not, alone or in combination with Jiang, teach or suggest each and every element of independent claims 1, 41, 53 and 56, a *prima facie* case of obviousness cannot be established with regard to any of independent claims 1, 41, 53 and 56.

In fact, Jiang teaches away from the concepts of Peery et al. (and the present invention), which are drawn to drug delivery devices and rate controlling membranes for use in the such devices. As such, there can be no suggestion to combine Peery et al. with Jiang. Hindsight reconstruction has been improperly used to argue obviousness using these particular references.

Since dependent claims 3, 10-13, 15, 16, 34-39, 47 and 59 include the elements of independent claim 1, 41, 53 or 56 and a *prima facie* case of obviousness cannot be established with regard to independent claim 1, 41, 53 or 56, a *prima facie* case of obviousness also cannot be established with regard to any of dependent claims 3, 10-13, 15, 16, 34-39, 47 and 59.

With further regard to dependent claims 13, 15, 16, 39 and 47, Peery et al. and Jiang do not alone or in combination teach or suggest the particular temperatures or times recited in the claims as required to establish obviousness.

A *prima facie* case of obviousness also cannot be established with regard to claim 36 since Peery et al. and Jiang do not alone or in combination teach or suggest an opioid analgesic drug in the drug-containing chamber as recited in claim 36.

A *prima facie* case of obviousness also cannot be established with regard to claim 37 since Peery et al. and Jiang do not, alone or in combination, teach or suggest an antiviral drug in the drug-containing chamber as recited in claim 37.

With further regard to claim 38, it cannot be rendered obvious since Peery et al. and Jiang do not alone or in combination teach or suggest an antineoplastic drug in the drug-containing chamber as recited in claim 38.

Reconsideration and withdrawal of the obviousness rejections of claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56 and 59 are requested.

**CONCLUSION**

Claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56 and 59 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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